DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M3150n

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-99-73

June 28, 1999

FACILITY ID #136987

Pedro Diaz-Bordon, M.D.
Medical Director
South Orlando OB-GYN Group
Diagnostic Center
2898 S. Osceola Avenue
Orlando, Florida 32806

Dear Dr. Diaz-Bordon:

Your facility was inspected on June 2, 1999, by a representative of the State of Florida, on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standard for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1:

Failure to have documentation that the interpreting physician, [redacted], meets the requirements of being certified by an FDA-recognized board or having the alternative of two months training in the interpretation of mammograms.

Level 2:

Failure to have documentation that the following interpreting physician, [redacted], meets the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months.

Failure to have documentation that the following interpreting physician, [redacted] meets the requirement of having a minimum of 40 CME credit hours of initial training in mammography.

The specific deficiencies noted above appear on the List of Observations which was issued to your facility on June 2, 1999. These deficiencies are symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulation action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000.00 for each failure to substantially comply with, or each day of failure to comply with the Standards.

- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.

- seek an injunction in Federal Court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time within which the correction will be completed.

Your reply should be directed to Carlos I. Medina, Compliance Officer, Food and Drug Administration, P. O. Box 592256, Miami, Florida 33159-2256, telephone number (305) 526-2800, ext. 921.

Sincerely,

Douglas D. Tolen
Director, Florida District